RULE 625 DISCUSSION

Rule Requirements and History

Rule 625 applies to existing equipment (operating prior to July 1, 1980) used in the manufacturing of synthesized pharmaceutical products. The rule requires various means of controlling volatile organic compounds (VOCs) such as low temperature condensers, vapor balance, enclosure of exposed liquid surfaces, covers on tanks, and leak repairs.

Rule 625 was promulgated in 1981 as part of Michigan's control strategy to address ozone. Non-attainment with the ozone air quality standards required under the federal Clean Air Act a State Implementation Plan (SIP) to reduce VOC emissions from various source types, including applying Reasonably Available Control Technology (RACT). Rule 625 was approved as part of the ozone RACT SIP in 1982. Revisions to Rule 625 were made in 1993 (1988 RACT 'Fix-up' SIP call) and 2000 (minor changes); these were also approved as SIP revisions.

ORR Recommendation A-15

Amend Rule 625 to provide that if a MACT standard applies to the sources identified in Rule 625 and also establishes VOC limitations, then the requirements of Rule 625 are not applicable.

Analysis

Rule 625 sets limitations on emissions and work practices for VOCs. A VOC is broadly defined as any carbon compound or mixture of carbon compounds that is photochemically reactive. The MACT regulations for pharmaceutical manufacturing includes both major and area source regulations that each address a listed number of Hazardous Air Pollutants (HAPs), a portion of which are VOCs. The MACT regulations do not cover all VOCs or all sources/equipment covered in Rule 625.

We asked for EPA reaction to the idea of allowing Rule 625-subject sources to substitute compliance with the (major or area source) MACTs for Rule 625 compliance. They were skeptical that general language would cover the range of circumstances that would occur with batch type operations, changes in product in individual pieces of equipment, when one regulation would apply instead of the other, and how and when an inspector would know which regulation was applicable. One of the EPA VOC experts suggest that perhaps use of a MACT as an alternate means of complying with Rule 625 could be added to the rule, available if the source is subject to one of the MACTs, not below the applicability cutoff or an exemption from the MACTs, a notification to AQD takes place, AQD approves, and AQD has delegation of authority for these MACTs (we do not have delegation). This looks to add about a page of language to Rule 625. EPA still had questions about the viability of this approach.

Rule 625 was developed from EPA's 1978 Control Technique Guideline (CTG) for this source category. Michigan has not considered updating the rule since no area is nonattainment for ozone. EPA recently made designations for the 0.075 ppm 8-hour NAAQS using 2008-2010 data, leaving Michigan as an attainment area. Use of 2009-

2011 or 2010-2012 data would show violations of the ozone NAAQS. EPA is currently conducting the 5 year review of the ozone NAAQS, which could lower the standard and will result in another round of designations. At the point when Michigan has to develop a SIP to address ozone nonattainment, further reductions in VOC emissions from this category may be considered along with other options for achieving the NAAQS.

AQD has access to the pharmaceutical manufacturing RACT regulations for Indiana and Illinois. While a stringency comparison with Rule 625 was not made, neither state has included a provision for use of MACT regulations as an alternative to RACT compliance.

Recommendation

AQD should consult with operators of Rule 625-subject facilities to explore the workability of the following options:

1. Leave Rule 625 as is.

2. Add provisions along the lines EPA suggests that provide the MACT-subject sources with a mechanism to use MACT compliance as an alternate means of compliance with Rule 625.

3. Wait until Michigan is required to update Rule 625 to meet updated RACT requirements or achieve VOC reductions as part of a SIP control strategy.